The opinion in support of the decision being entered today is not binding precedent of the board

Paper 20

UNITED STATES PATENT AND TRADEMARK OFFICE

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PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ELLINGTON M. BEAVERS, DJOERD HOEKSTRA, YEE SAN SU and NICOLE WILLARD

Appeal 2001-2539[1]
Application 09/118,730[2]

Before: WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and McKELVEY, Senior Administrative Patent Judge.

McKELVEY, Senior Administrative Patent Judge.

Decision on appeal under 35 U.S.C. § 134

The appeal is from a decision of a primary examiner rejecting claims 1-8 and 20-23. We vacate and remand.

A. Findings of fact

The record supports the following findings by at least a preponderance of the evidence.[3]

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[1] The application on appeal was received at the board on 23 August 2001.

[2] Application for patent filed 17 July 1998. The application appears to be a continuation-in-part of application 08/781,308, filed 15 January 1997, now U.S. Patent 5,789,571. The real party in interest is Biocoat Incorporated.

[3] To the extent these findings of fact discuss legal issues, they may be treated as conclusions of law.

The invention

1. The claimed invention relates to a composition of matter (1) identified as "medical grade" hyaluronic acid in free-acid form (as opposed in its sodium salt form) and (2) defined by a process by which it is made.

2. A "medical grade" hyaluronic acid in its free-acid form is a material which can appropriately be used in the body.

3. Applicants have already received a patent to the process for making "medical grade" hyaluronic acid in its free-acid form. U.S. Patent 5,789,571.

The examiner's rejection

4. The examiner has rejected claims 1-8 and 20-23 as being unpatentable under 35 U.S.C. § 103(a) over Schultz, U.S. Patent 4,808,576, issued 28 February 1989.

5. Schultz is prior art vis-a-vis applicants under 35 U.S.C. § 102(b).

6. According to the examiner, Schultz describes hyaluronic acid in its free-acid form, as well as its sodium salt form. Likewise said to be described are methods for using hyaluronic acid in its free-acid form in the treatment of horses.

The dispute on appeal

7. What surfaces from the (1) Appeal Brief (Paper 16), (2) Examiner's Answer (Paper 17) and (3) Reply Brief (Paper 18) is a question of whether "medical grade" hyaluronic

acid in its free-acid form is anticipated by any prior art within the scope of 35 U.S.C. § 102(b).

8. While the examiner's rejection is said to be based on 35 U.S.C. § 103(a), the fact of the matter is that the examiner is maintaining that applicants' claimed composition is not novel.

9. Applicants say their claimed composition is novel and that Schultz cannot possibly describe hyaluronic acid in its free-acid form--according to applicants, Schultz does not describe a method which would enable a person having ordinary skill in the art to make hyaluronic acid in its free-acid form.

10. Applicants go on to say that most literature discussing hyaluronic acid is really talking about hyaluronic acid in its sodium-salt form.

11. Furthermore applicants tell us hyaluronic acid in its free-acid form is not available as a commercial product.

12. Much of applicants position is based on declarations of named inventor Ellington M. Beavers. The Beavers declaration attempts to make several points, including the following:

a. One purpose of the declarations was "to establish, by experimental evidence, that the product produced by the process of the present invention is significantly and patentably different from products made by processes disclosed in the prior art" (Beavers declaration dated 17 July 1998, ¶ 2).

b. The only hyaluronic acid in its free-acid form which can appropriately be used in the body is hyaluronic acid made in accordance with the method set out in claim 1 and those claims on appeal (Beavers declaration dated 9 July 1999, ¶ 2).

c. Professionals, professional journals and others have imprecisely used the term "hyaluronic acid" when they meant to use, and should have used, the term "sodium salt of hyaluronic acid" (Beavers declaration dated 9 July 1999, ¶ 3).

d. Attempts are said to have been made by applicants' assignee to obtain hyaluronic acid in its-free acid form from at least seven (7) "major suppliers in the field" including (1) Lifecore Biomedical, (2) Sigma Chemical, (3) Aldrich Chemical, (4) Fluka Chemical, (5) Acros Organics (Fisher Scientific), (5) VWR Scientific Products and (7) Polysciences. Five of the suppliers are said to have said that they did not sell hyaluronic acid in its free-acid form. After an inquiry is said to have been made to "the technical department", personnel at Fluka Chemical is said to have said that Fluka did not sell hyaluronic acid in its free-acid form notwithstanding it was product listed--apparently erroneously--in one of its catalogs. Personnel at Fluka Chemical are said to have said that Fluka Chemicals intended to correct its catalogs. Another unidentified supplier is said to have insisted that it made, and sold, a hyaluronic acid in its free-acid form, but when applicants obtained a sample of the product made and sold by the

unidentified supplier, "we determined that it was the sodium salt, not the free acid."[4] See Beavers declaration dated 9 July 1999, ¶ 7).

The Merck Index

13. In the Examiner's Answer, and purporting to respond to arguments presented in the Appeal Brief, the examiner for the first time during the prosecution cites The Merck Index, page 813, entry 4793 (12th ed. 1996) (hereinafter "Merck") (Examiner's Answer, page 4).

14. In their Reply Brief, and not without some justification, applicants express (pages 1-2) "surprise" given that the examiner had not previously relied on Merck. Applicants "offer to submit a further Declaration, giving the pertinent factual details" (Reply Brief, page 2).

15. Merck entry 4793 lists "Hyaluronic Acid". In a section entitled "Isoln [, i.e., isolation,] and characterization", Merck cites:

a. Meyer, Palmer, J. Biol. Chem. **107**, 629 (1934);

b. Balazs, Fed. Proc. **17**, 1086 (1958);

c. Laurent et al., Biochim. Biophys. Acta **42**, 476 (1954);

d. Meyer, Fed Proc. **17**, 1075 (1958).

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[4] We decline to give much weight to the discussion in the Ellington declaration with respect to the unidentified supplier. First, the supplier is not identified. Second, there is no contemporaneous laboratory notebook or other documentary evidence describing how a product was analyzed or any results of those analysis.

16. A structure shown in Merck would appear to be a free-acid form. Note the free —COOH groups.

17. Following the structure, there is discussion of the "sodium salt".

18. None of the articles mentioned in Merck has been discussed on the record.

Schultz

19. Schultz also contains a discussion of hyaluronic acid and a reference to (1) two Rydell articles, (2) a Peyron article (which may well deal with the sodium-salt form given the "Na" in its title) and (3) Balazs, U.S. Patent 4,141,973.

20. Insofar as we can tell, the Rydell articles, the Peyron article and the Balazs patent have not been discussed on the record.

B. Discussion

The appeal is interesting from the point of view that applicant presents a facially reasonable case in its Appeal Brief in support of reversal and the examiner responds with an equally reasonable case in support of affirmance. There was not much applicants could do in the Reply Brief to respond to Merck given that additional evidence is not normally authorized in a reply brief.

The Merck Index is an authority relied upon in the USPTO and is a publication which our board has found to be highly credible over many years. That does not mean, of course, that The Merck

Index might not contain an error. We would suppose errors have been found from time to time in The Merck Index and we would have every expectation that they would be corrected. However, in the face of the content of Merck, as relied upon by the examiner, we have considerable doubt that the Beavers declarations respond to answer the obvious point that Merck discusses both (1) hyaluronic acid and (2) the sodium salt-form of that acid. Manifestly, neither applicants nor the examiner have discussed all the various articles cited in both Schultz and Merck. We think applicant and the examiner should address those articles in the first instance.

We do not disagree with applicants' position that a reference must be enabling. Likewise, at this point, we take no position of whether any of the articles cited in Merck and Schultz fail to enable a person having ordinary skill in the art to make a "medical grade" hyaluronic acid in free-acid form.

Given the state of the record as we find it on appeal, it is apparent that further prosecution is in order. That prosecution best takes place before the examiner where additional documents, declarations and amendments may be made. Accordingly, we vacate the examiner's rejection and remand for further proceedings not inconsistent with the views expressed herein.

We would make a suggestion to applicants in this particular case that consideration be given to retaining an independent "expert" who might review all the documentation and provide an opinion on the issue of whether any of the documents of record

and the articles cited by Schultz and Merck describe a "medical grade" hyaluronic acid in its acid-free form. By our suggestion, we do not impugn the integrity of the declaration testimony of Beavers. We only suggest that an opinion of an independent expert, with no axe to grind, so to speak, might be accorded more weight. Any expert, of course, should state the underlying scientific basis for any opinion. Applicants have a reasonably heavy burden and the presentation of evidence more in the form of a scientific "peer review" might be more convincing. Nevertheless, we leave the nature of any evidence to be filed by applicants to their discretion.

C. Decision and order

Upon consideration of the appeal, and for the reasons given, it is

ORDERED that the decision of the examiner rejecting claims 1-8 and 20-23 is vacated.[5]

[5] See Ex parte Zambrano, 58 USPQ2d 1312 (Bd. Pat. App. & Int. 2001), for explanation of the effect of a board decision vacating an examiner's rejection.

FURTHER ORDERED that the application on appeal is remanded is the examiner for action not inconsistent with the views expressed in this opinion.

VACATED AND REMANDED

SHERMAN D. WINTERS
Administrative Patent Judge

WILLIAM F. SMITH
Administrative Patent Judge

FRED E. McKELVEY, Senior
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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